

CLAIM SUMMARY DOCUMENT:

Claim 1. (Currently Amended) A method for producing a controlled-release pharmaceutical preparation with a particle-containing coating comprising the steps of:

- a) preparing a drug-containing solid core;
- b) suspending a pore-forming agent having a balanced solubility below 50 mg/ml in an aqueous dispersion of a film-forming, essentially water insoluble polymer in order to form a coating suspension having a predetermined amount of solid particles of the pore-forming agent suspended therein
- c) coating the solid core with the obtained suspension; and
- d) drying the coated tablet;

wherein the pore-forming agent is soluble in body fluids;

wherein the mean particle size of the pore-forming agent is 0.5-100 μ m; and

wherein the amount of the pore-forming agent is 40-95% by weight of the total weight of the dry coating.

Claim 2. (Currently Amended) A method according to claim 1, wherein the solubility of the pore-forming agent is ~~below 100 mg/ml, preferably below 50 and most preferably below 30 mg/ml~~ in the aqueous coating dispersion.

Claim 3. (Currently Amended) A method according to claim 1, wherein the mean particle size of the pore-forming agent is 1-25 ~~0-1-500~~ μm .

Claim 4. (Previously Presented) A method according to claim 1, wherein the pore-forming agent is selected from a group consisting of potassium salts, calcium salts, magnesium salts, amino acids, weak acids, carbohydrates, polymers with amino and/or acid functions or a composition wherein at least one of the components is selected from one of these groups.

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Claim 5. (Previously Presented) A method according to claim 1, wherein the pore-forming agent is potassium bitartrate, creatine, asparagine, glutamine, aspartic acid, glutamic acid, leucin, neroleucine, inosine, isoleucine, magnesium citrate, magnesium phosphate, magnesium carbonate, magnesium hydroxide, magnesium oxide or a composition wherein at least one component is selected from one of these substances.

Claim 6. (Previously Presented) A method according to claim 1, wherein the pore-forming agent is chitosan and poly(butyl methacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate) 1:2:1.

Claim 7. (Previously Presented) A method according to claim 1, wherein the water insoluble polymer is selected from one of the groups of cellulose esters, acrylic

polymers, polyvinyl acetates, polyvinyl chlorides or a composition wherein at least one component is selected from one of the groups.

Claim 8. (Previously Presented) A method according to claim 1, wherein the coating polymer is ethylcellulose, celluloseacetate, celluloseacetatebutyrate, celluloseacetatepropionate, nitrocellulose, polymethylmethacrylate, poly(ethylacrylate, methylmetacrylate), polyvinylacetate, polyvinylchloride, polyethylene, polyisobutylene, poly(ethylacrylate, methylmetacrylate, trimethylammonioethylmetacrylatchloride), a block- or copolymer of the polymers or a composition wherein at least one of the components is selected from these polymers.

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Claim 9. (Previously Presented) A method according to claim 1, wherein the coating polymer is a copolymer consisting of 50-100% by weight of polyvinyl chloride and 0-50% by weight of polyvinyl acetate.

Claim 10. (Previously Presented) A method according to claim 1, wherein the coating polymer is a copolymer consisting of 80-95% by weight of polyvinylchloride, 0,5-19% by weight of polyvinylacetate and 0,5-10% by weight of polyvinylalcohol.

Claim 11. (Previously Presented) A method according to claim 1, wherein the solid core includes at least one drug selected from the group consisting of tranquillizers, antibiotics, hypnotics, antihypertensives, antianginas, analgesics, antiinflammatorics,

neuroleptics, antidiabetics, diuretics, anticholinergics, antihyperacidics or antiepileptics, ACE inhibitors β -receptor antagonists and agonists, anaesthetics, anorexiant, antiarrhythmics, antidepressants, anticoagulants, antidiarrhoetics, antihistamines, antimalarials, antineoplastics, immunosuppressives, antiparkinsonians, antipsychotics, antiplatelets, diuretics, antihyperlipidics.

Claim 12. (Previously Presented) A method according to claim 1, wherein the drug for the solid core is potassium chloride, theophylline, a theophylline salt, phenylpropanolamine, sodium salicylate, choline theophyllinate, paracetamol, carbidopa, levodopa, diltiazem, enalapril, verapamil, naproxen, pseudoephedrin, nicorandil, oxybutin, morphine, oxycodone or propranolol.

Claim 13. (Previously Presented) A method according to claim 1, wherein the aqueous dispersion includes at most 20%, preferably at most 10% and most preferably at most 5% by weight of organic solvent.

Claim 14. (Previously Presented) A method according to claim 1, wherein the obtained coated cores are cured with heat or moisture.

Claim 15. (Previously Presented) A method according to claim 1, wherein the pore-former in the coating suspension is stabilized with one or more ionic, non-ionic or polymer surfactants.

Claim 16. (Previously Presented) A method according to claim 1, wherein the coating polymer is plasticized.

Claim 17. (Original) A controlled-release pharmaceutical preparation including a drug-containing solid core having a coating thereon, said coating essentially consisting of a water insoluble polymer with a predetermined amount of particles of a water soluble, pore-forming agent dispersed therein, wherein the pore-forming agent is selected from the group consisting of potassium bitartrate, creatine, aspartic acid, glutamic acid and inosine.

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Claim 18. (Original) A controlled-release pharmaceutical preparation including a drug-containing solid core having a coating thereon, said coating essentially consisting of a water insoluble polymer with a predetermined amount of particles of a water soluble, pore-forming agent dispersed therein, wherein the pore-forming agent is selected from the group consisting of asparagine, glutamine leucin, neroleucine, isoleucine, magnesium phosphate, magnesium carbonate, magnesium hydroxide, chitosan and poly (butyl methacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate) 1:2:1 or a composition wherein at least one component is selected from one of these substances.

Claim 19. (Currently Amended) Preparation according to claim 17, wherein the amount of the pore-forming agent is ~~40-95, preferable 50-90% and most preferably 55-88%~~ by weight of the total weight of the dry coating.

Claim 20. (Previously Presented) Preparation according to claim 17, wherein the polymer is ethylcellulose, cellulose-acetate, celluloseacetatebutyrate, celluloseacetatepropionate, nitrocellulose, polymethylemethacrylate, poly(ethylacrylate, methylmetacrylate), polyvinylacetate, polyvinylchloride, polyethylene, polyisobutylene, poly(ethylacrylate, methylmetacrylate, trimethylamonioethylmetacrylatchloride), a block-or copolymer of the polymers or a composition wherein at least one of the components is selected from these polymers.

cancel Claim 21. (Previously Presented) Preparation according to claim 17, wherein the coating polymer is a copolymer consisting of 50-100% by weight of polyvinyl chloride and 0-50% by weight of polyvinyl acetate.

Claim 22. (Previously Presented) Preparation according to claim 17, wherein the coating polymer is a copolymer consisting of 80-95% by weight of polyvinylchloride, 0,5-19% by weight of polyvinylacetate and 0,5-10% by weight of polyvinylalcohol.

Claim 23. (Canceled)

Claim 24. (Canceled)

Claim 25 (New) The preparation according to claim 17, wherein the amount of the pore-forming agent is 55-88% by weight of the total weight of the dry coating.
